

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
THIS DOCUMENT RELATES TO: WAVE 8 CASES ON ATTACHED EXHIBIT “A”	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**MEMORANDUM IN SUPPORT OF PLAINTIFFS’ MOTION TO EXCLUDE
CERTAIN OPINIONS AND TESTIMONY OF PETER SAND, M.D.**

Pursuant to Federal Rules of Evidence 702, 403, and 104, Plaintiffs respectfully request that the Court exclude certain opinions and testimony of Defendants’ expert, Peter Sand, M.D. (“Dr. Sand”). In support of their Motion, Plaintiffs state as follows:

INTRODUCTION

Dr. Peter Sand is an Obstetrician/Gynecologist with a subspecialty in Female Pelvic Medicine and Reconstructive Surgery, and Plaintiffs do not challenge his qualifications as such.¹ Dr. Sand’s general report sets forth opinions on liability issues with regard to the TVT Retropubic (“TVT”), including the TVT design and material properties, as well as the safety and efficacy of the TVT. However, Dr. Sand has no experience designing transvaginal mesh devices and has not used the TVT device in his practice for eleven or more years. Dr. Sand’s experience in the field of Obstetrics and Gynecology and Urogynecology does not render all of his opinions admissible. The admission of Dr. Sand’s baseless opinions would be contrary to law and would present a significant

¹ See Wave 8 TVT General Expert Report of Peter Sand, M.D. at p. 1 (Ex. B to Motion).

risk of confusing the issues and misleading the jury.² As this Court has noted, “[j]ust because an expert may be ‘qualified . . . by knowledge, skill, experience, training or education’ does not necessarily mean that the opinion that the expert offers is ‘the product of reliable principles and methods’ or that the expert ‘has reliably applied the principles and methods to the facts of this case.’”³ Accordingly, Dr. Sand should be prevented from offering testimony or opinions that exceed those permitted under *Daubert* and its progeny. Specifically, this Court should exclude Dr. Sand’s opinions regarding: (1) the design and material properties of the TVT Retropubic mesh device; and (2) the safety and efficacy of the TVT Retropubic device.

LEGAL STANDARD

Under Rule 702 of the Federal Rules of Evidence, as interpreted by the Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), an expert witness may be qualified by “knowledge, skill, experience, training or education.” Fed. R. Evid. 702. The witness’s testimony also must represent “scientific knowledge,” meaning that it is supported by appropriate validation; and it must assist the jury, meaning that it must be relevant. *United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir. 1995). Expert testimony is admissible if the expert is proven to be qualified and said testimony (1) “will help the trier of fact to understand the evidence or to determine a fact in issue,” (2) is “based upon sufficient facts or data,” (3) is “the product of reliable principles and methods” and (4) has been reliably applied “to the facts of the case.” Fed. R. Evid. 702. Opinion evidence may be admitted if it “rests on a reliable foundation and is relevant.” *Daubert*, 509 U.S. at 597. In the end, an expert’s testimony is admissible if it “rests on a reliable foundation and is relevant.” *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999).

² See *Westberry v. GislavedGummi AB*, 178 F.3d 257, 261 (4th Cir. 1999) (“[T]he court must recognize that due to the difficulty of evaluating their testimony, expert witnesses have the potential to ‘be both powerful and quite misleading.’”) (citing *Daubert*, 509 U.S. at 596).

³ *Cisson v. C.R. Bard, Inc.*, MDL No. 2187, 2013 U.S. Dist. LEXIS 78061, *42-43 (S.D.W.V. 2013).

The duty rests with the Defendants to “come forward with evidence from which the court can determine that the proffered testimony is properly admissible.” *Maryland Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). Even if Dr. Sand is qualified and his testimony is reliable, “testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful.” *In re Ethicon, Inc., Pelvic Repair Sys. Products Liab. Litig.*, 2:12-MD-02327, 2014 WL 186872 (S.D.W. Va. Jan. 15, 2014) *reconsideration denied*, 2014 WL 457544 (S.D.W. Va. Feb. 3, 2014). In other words, his testimony must “fit” the case, and there must be a “valid scientific connection to the pertinent inquiry as a precondition to admissibility. *Id.*

ARGUMENT

I. Dr. Sand’s General Opinions on the Design and Material Properties of the TVT Should Be Precluded or Limited.

Dr. Sand does not have any experience in biomaterials engineering and has never designed polypropylene mesh devices; however, he arbitrarily offers baseless opinions regarding the design and material properties of Ethicon’s TVT device.⁴ Specifically, he states that he is “not aware of any valid medical research or literature” supporting “degradation or cytotoxicity of polypropylene” and he has not experienced this in his clinical practice.⁵ Quoting Carl Sagan, this Court has noted that “[a]bsence of evidence is not evidence of absence’.”⁶ This Court further noted: “Sagan’s aphorism illustrates the logical fallacy that a premise is not necessarily true merely because it has yet to be proven false.”⁷ Applying Sagan’s logic, Dr. Sand’s opinions on the material properties of the TVT mesh are baseless and should be rejected.

Further, as stated, Dr. Sand is not qualified to opine on the design and material properties of

⁴ See Ex. B at pp. 1, 8, 12-13; 9/26/18 Sand Dep. at 33:6-36:24 (Ex. C to Motion).

⁵ Ex. B at p. 12.

⁶ *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 501, 583-84 (S.D.W.V. 2014).

⁷ *Id.*

the TVT. Though he testified that *he believes* that he is a biomaterials expert,⁸ his basis for this statement is his “*clinical experience* as well as [his] *basic science research experience*.”⁹ This vague and ill-defined response makes clear that Dr. Sand is not qualified to opine on the material properties of TVT mesh under the *Daubert* standard. When asked whether he has ever observed a difference between TVT mesh that was laser cut versus mechanically cut, Dr. Sand testified that he did not believe that he had ever used the laser cut TVT mesh in a patient and he “*probably* could tell the difference.”¹⁰ Dr. Sand is a board-certified Obstetrician/Gynecologist with a practice focused on female urology and pelvic floor medicine.¹¹ Dr. Sand does not have any specialized education, training, or experience related to the design or material properties of polypropylene mesh devices.¹²

Further, when asked whether he reviewed any of Ethicon’s design specifications, Dr. Sand testified:

A. Gee, I’m not sure I understand what design specifications would be relative to what I read about.¹³

Essentially, Dr. Sand has no knowledge of the scientific and material properties of Ethicon’s pelvic mesh devices, including the TVT. Despite this lack of knowledge, education, experience, and training about the design and material properties of polypropylene mesh devices, Dr. Sand attempts to opine on design and material properties of the pelvic mesh products, including degradation, cytotoxicity, and cut (laser or mechanical). These opinions undoubtedly exceed the bounds of his qualifications, are based on no objective criteria, and should be precluded under *Daubert*.

⁸ Ex. C at 80:18-24.

⁹ *Id.* (emphasis added).

¹⁰ *Id.* at 85:5-86:1 (emphasis added).

¹¹ See Ex. B at p. 1.

¹² *Id.*; see also Curriculum Vitae of Peter K. Sand, M.D. (Ex. D to Motion).

¹³ Ex. C at 32:19-22.

II. Dr. Sand's General Opinions on the Safety and Efficacy of the TVT Should Be Precluded or Limited.

Dr. Sand should be precluded from offering any opinions regarding the safety and efficacy of the TVT device because he has not used the TVT Retropubic in his practice since 2005, 2006 or 2007 – *eleven or more years ago* – and despite having the TVT Retropubic readily available to him in his practice for a period of 7 to 10 years, he chose not to use it, selecting a competitor's product instead.¹⁴ Dr. Sand's use of mesh products generally, and his qualifications as a gynecologist and pelvic floor surgeon do not, by themselves, uniquely qualify him to opine regarding the safety and efficacy of a specific transvaginal mesh device. In his report, Dr. Sand cites to a handful of medical articles in support of his opinion that the TVT Retropubic is safe and effective but, of note, the bulk of the articles to which he cites address the safety and/or efficacy of transvaginal mesh slings generally and are not limited to the TVT Retropubic.¹⁵ A review of the literature does not provide a sufficient basis for Dr. Sand to offer a reliable design opinion unless he can identify an appropriate standard that he applied. *See Winebarger v. Boston Scientific Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *14 (S.D. W. Va. Apr. 24, 2015) (finding that Dr. Schull had not reliably applied the principles learned through his experience and the literature to the facts of this case because he had not seen any standard operating procedures or design protocols for the development of the medical device in question).

Nowhere does Dr. Sand identify any objective standard applied by him, or by which his opinions on safety and efficacy can be tested or objectively evaluated. As such, he should be precluded from giving any opinions related to the adequacy of the design, safety, and efficacy of the TVT.

¹⁴ *Id.* at 123:21-125:4.

¹⁵ Ex. B at pp. 15-20.

Further, Dr. Sand has reviewed some of the documents listed on his “reliance list” – which was prepared by defense counsel – but he testified that he has not reviewed all of them and has not reviewed a single corporate witness deposition.¹⁶ With respect to corporate witness depositions, Dr. Sand testified that they “might” be a basis for his opinions “when [he] has a chance to review them in the future”¹⁷ Further, he testified that he asked for corporate witness depositions, but did not review them prior to preparing his general report.¹⁸ Notably, he testified as follows:

Q. Doctor, why did you request the depositions of Ethicon employees after reading Dr. Rosenzweig’s report?

A. Well, because I realized that Bruce had - - was referring to a lot of information I wasn’t aware of, internal documents from Ethicon as well as some information from these depositions, and so I was asking where did this come from and I need to have this information to review. I just didn’t have the time to review all of the information.¹⁹

Dr. Sand’s testimony makes clear that his reliance list does not contain an accurate list of the facts or data considered by him in forming his opinions as required by F.R. Civ. P. 26(a)(2)(B)(ii). Dr. Sand testified that his reliance list was put together by counsel for Defendants and contains materials that he did not actually review. This violates F.R. Civ. P. 26(a)(2)(B)(ii) and leaves Plaintiffs with an incomplete understanding of the facts and materials Dr. Sand utilized to support his opinions. More importantly, Dr. Sand testified that he asked for certain documents and information that he was unaware of because he “need[ed] to have this information to review,” but he did not review those documents and information.

Dr. Sand did not actually review or rely on any objective standard for his opinions that the TVT is safe and effective. Further, he failed to disclose what literature and other materials he relied

¹⁶ Ex. C at 21:5-12, 18-19.

¹⁷ *Id.* at 22:3-8.

¹⁸ *Id.* at 22:11-17.

¹⁹ *Id.* at 23:4-13.

upon and, more importantly, he has not reviewed documents and information that he testified he needs to review. Therefore, the appropriate remedy is to disallow Dr. Sand's opinions regarding the safety and efficacy of the TVT, as well as his opinions regarding the TVT design and material properties (as set forth above).

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the Court exclude the Dr. Sand's opinions and testimony regarding: (1) the design and material properties of the TVT Retropubic device; and (2) the safety and efficacy of the TVT Retropubic device.

Dated: October 18, 2018

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing document on October 18, 2018, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

Respectfully submitted,

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